

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS	)	
CORPORATION,	)	
	)	
Plaintiff	)	
	)	C.A. No. 23-975 (RGA) (SRF)
v.	)	
	)	
LIQUIDIA TECHNOLOGIES, INC.,	)	
	)	
Defendant.	)	

**PLAINTIFF'S MEMORANDUM IN SUPPORT OF  
ITS MOTION FOR JUDGMENT ON PARTIAL FINDINGS UNDER RULE 52(C)**

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Plaintiff United Therapeutics Corporation (“UTC”) moves under Federal Rule of Civil Procedure 52(c) for judgment on partial findings that Defendant Liquidia Technologies, Inc. (“Liquidia”) has failed to prove that claim 14 of U.S. Patent No. 11,826,327 (the “’327 patent”) is invalid.

## **I. SUMMARY OF ARGUMENT**

Liquidia has offered a sole invalidity defense—one obviousness combination—with respect to claim 14 of the ’327 patent, but controlling law forecloses that defense. Liquidia’s obviousness combination requires Faria-Urbina 2018, U.S. Patent No. 10,716,793 (the “’793 patent”), and Saggar 2014. This combination necessarily fails because the ’793 patent is not prior art.

Section 102 defines two categories of prior art, § 102(a)(1) and (a)(2), and the ’793 patent does not qualify under either. The ’793 patent issued after the effective priority date of the ’327 patent, so it cannot qualify under § 102(a)(1). The ’793 patent cannot qualify under § 102(a)(2) because it is excluded by the common ownership exception defined in § 102(b)(2)(C). A disclosure in a patent “shall not be prior art” under § 102(a)(2) if “the subject matter disclosed and the claimed invention, not later than the effective filing date of the claimed invention, were owned by the same person or subject to an obligation of assignment to the same person.” 35 U.S.C. § 102(b)(2)(C). Here, the ’793 and ’327 patents (and underlying applications) were both owned by UTC not later than the effective filing date of the ’327 patent. Accordingly, the ’793 patent “shall not be prior art.” *Id.*

Because Liquidia’s only invalidity defense against claim 14 of the ’327 patent is premised upon the ’793 patent and the ’793 patent is not prior art, this Court should enter judgment against Liquidia regarding validity of claim 14.

## II. NATURE AND STAGE OF THE PROCEEDINGS

UTC filed its First Amended Complaint alleging infringement of the '327 patent on November 30, 2023. D.I. 8. Liquidia answered the First Amended Complaint and Counterclaims on January 8, 2024. D.I. 12. The Pretrial Conference was held on May 30, 2025. Trial began on June 23, 2025, and Liquidia rested its case in chief regarding invalidity on June 25, 2025. Liquidia conceded infringement of claims 1 and 14 of the '327 patent. Ex. D (Trial Tr. (Vol. I)) 28:4–7. Liquidia's only defense to claim 14 is a single, three-reference obviousness combination: Faria-Urbina 2018, the '793 patent, and Saggar 2014.<sup>1</sup>

## III. STATEMENT OF FACTS

The '327 patent issued from U.S. Patent Application No. 17/233,061 (the "'061 application"), which was filed on April 16, 2021. The '327 patent claims priority to two provisional applications: (1) U.S. Provisional Patent Application No. 63/011,810 (the "'810 provisional"), filed on April 17, 2020; and (2) U.S. Provisional Patent Application No. 63/160,611, filed on March 12, 2021. Ex. G ('327 patent, JTX-0001) at 1 (60). Thus, the earliest effective priority date of the '327 patent is April 17, 2020.<sup>2</sup> UTC is listed as the applicant and assignee on the face of the '327 patent. *Id.* at (73). UTC owns the '327 patent and has owned that patent and the underlying applications at all times, and all named inventors are UTC employees with an obligation to assign inventions to UTC. Ex. D, 36:3–21 (Byrd). The '327 patent issued with, among others, the following claims:

1. A method of improving exercise capacity in a patient having pulmonary hypertension associated with interstitial lung disease, comprising administering by

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<sup>1</sup> Liquidia elected this three-reference combination as one of its defenses, but only applies two references, Faria-Urbina and the '793 patent, to claim 14.

<sup>2</sup> Liquidia expressly waived any challenge to the effective priority date of the '327 patent shortly before trial as confirmed at the Pretrial Conference. Ex. A (Pretrial Conf. Tr. 9:7–13).

inhalation to the patient having pulmonary hypertension associated with interstitial lung disease an effective amount of at least 15 micrograms up to a maximum tolerated dose of treprostinil or a pharmaceutically acceptable salt thereof in a single administration event that comprises at least 6 micrograms per breath.

**11.** The method of claim 1, wherein said administering is performed by a pulsed inhalation device.

**14.** The method of claim 11, wherein the pulsed inhalation device is a dry powder inhaler comprising a dry powder comprising treprostinil or a pharmaceutically acceptable salt thereof.

JTX-0001 at 50, claims 1, 11, 14.

The '793 patent issued on July 21, 2020—after the effective priority date of the '327 patent—from U.S. Patent Application 16/778,662 (“the '662 application”), which was filed January 31, 2020. The '793 patent claims priority to U.S. Provisional Patent Application No. 60/800,016 (the “'016 provisional”), filed on May 15, 2006. Ex. H ('793 patent, DTX0002) at 1 (22). UTC is listed as the applicant and assignee on the face of the '793 patent. *Id.* at (71), (73). UTC owned the '662 application (and the resulting '793 patent) on the day it was filed and at all times since. Ex. D, 36:3–21 (Byrd).

#### **IV. LEGAL STANDARD**

Under Federal Rule of Civil Procedure 52(c), “[i]f a party has been fully heard on an issue during a nonjury trial and the court finds against the party on that issue, the court may enter judgment against the party on a claim or defense that, under the controlling law, can be maintained or defeated only with a favorable finding on that issue.” In deciding whether to enter judgment on partial findings under Rule 52(c), the Court is not required to draw any inferences in favor of the non-moving party; rather, the Court may make findings in accordance with its own view of the evidence. *See DLJ Mortg. Cap., Inc. v. Sheridan*, 975 F.3d 358, 371–72 (3d. Cir. 2020). When the defendant’s evidence presented at a bench trial fails to support invalidity, an invalidity defense is properly resolved under a Rule 52(c) motion. *Yamanouchi Pharm. Co. v. Danbury Pharmacal*,

*Inc.*, 231 F.3d 1339, 1346 (Fed. Cir. 2000); *Bayer Pharma AG v. Watson Labs., Inc.*, 183 F. Supp. 3d 579, 584 (D. Del. 2016).

“Obviousness rests on several critical factual underpinnings: (1) the scope and content of the prior art, (2) the differences between the prior art and the claimed invention, (3) the level of skill in the art, and (4) the objective indicia of nonobviousness.” *Yamanouchi*, 231 F.3d at 1343. Where a combination of references fails to teach all the elements of a claim, there is no *prima facie* case of obviousness. *In re Glatt Air Techniques, Inc.*, 630 F.3d 1026, 1030 (Fed. Cir. 2011). The party challenging a patent bears the burden to show that a reference is prior art by clear and convincing evidence. *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1576 (Fed. Cir. 1996).

## V. ARGUMENT

Liquidia has not offered a legally cognizable defense to claim 14 of the ’327 patent. Liquidia’s sole defense—an obviousness combination—relies on only the ’793 patent to teach the “dry powder inhaler” element of claim 14. Yet the ’793 patent is not prior art. It issued after the effective priority date of the ’327 patent, so it cannot be prior art under § 102(a)(1). Likewise, it “shall not be prior art” under § 102(a)(2) because the exception created by § 102(b)(2)(C)—common ownership—applies to the ’793 patent. Because the ’793 patent is not prior art to the ’327 patent, Liquidia has not and cannot prove invalidity of claim 14.

### A. Liquidia’s sole invalidity defense to claim 14 is an obviousness combination dependent on the ’793 patent.

As Liquidia made clear at the Pretrial Conference, its only invalidity defense applicable to claim 14 of the ’327 patent is obviousness. Ex. A (Pretrial Conf. Tr.) at 7:19–23; 11:21–12:8. And Liquidia identified only one obviousness combination, based on the combination of Faria-Urbina 2018, the ’793 patent, and Saggar 2014. D.I. 318; 361. Dr. Channick offered no anticipation or



written description opinions that related to claim 14. Ex. E (Trial Tr. Vol. II) 509:24–510:2; 522:18–23. Accordingly, Liquidia challenges the validity of claim 14 only through obviousness.

The only reference in its obviousness combination that Liquidia relies on to show the elements of claim 14 is the '793 patent. Liquidia relies on not just the disclosure of the '793 patent but also the issued claims to fill this gap in the other references. Ex. E (Trial Tr. Vol. II) 475:2–9; *see also* D.I. 251-1 (Defendant's Final Invalidity Contentions Table of Contents § VII) at 69–71. Thus, the '793 patent is essential to the combination.

**B. The '793 patent is not prior art to the '327 patent.**

**1. The scope of prior art is defined by 35 U.S.C. § 102.**

The America Invents Act (“AIA”) provides that “[a] person shall be entitled to a patent unless—”

(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or

(2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

35 U.S.C. § 102(a).<sup>3</sup> These two provisions are related but different. Prior art under § 102(a)(1) in a printed publication may include “an issued patent, a published application, and a non-patent printed publication.” Manual of Patent Examination & Procedure (“MPEP”) § 2152. But under § 102(a)(2), only “U.S. patent documents” are prior art. *Id.* Section 102(b)(2)(C) further modifies what is and is not prior art under § 102(a)(2): the “common ownership” exception carves out of

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<sup>3</sup> The AIA version of 35 U.S.C. § 102 applies because the '327 patent has an earliest claimed priority date after the effective date of the AIA, March 16, 2013.

§ 102(a)(2) any disclosure where “the subject matter disclosed and the claimed invention, not later than the effective filing date of the claimed invention, were owned by the same person or subject to an obligation of assignment to the same person.” 35 U.S.C. § 102(b)(2)(C).

Thus, a reference patent or patent application that was published after the effective filing date of the challenged patent or application cannot be prior art under § 102(a)(2) where the reference was commonly owned or subject to common obligation to assign on the effective filing date of the challenged patent—*even if* it was filed before the effective filing date of the challenged patent. 35 U.S.C. § 102(b)(2)(C). For example, in *Sanofi Pasteur Inc. v. Pfizer, Inc.*, the Patent Trial and Appeal Board found that two reference patents were not prior art and could not be used as anticipation or obviousness references because the reference patents were commonly owned by the owner of the challenged patent and thus were excepted from the prior art by § 102(b)(2)(C). Ex. C (IPR2018-00188, Paper 10) at 13–15. The MPEP reinforces that § 102(b)(2)(C) excepts from the prior art any patents that are commonly owned or under subject of assignment to the owner of an application.<sup>4</sup> For example, MPEP § 717.02 explains that:

35 U.S.C. 102(b)(2)(C) provides that a disclosure made in a U.S. patent . . . shall not be prior art to a claimed invention under 35 U.S.C. 102(a)(2) if, not later than the effective filing date of the claimed invention, the subject matter disclosed and the claimed invention were owned by the same person or subject to an obligation of assignment to the same person . . . Thus, the AIA provides that certain prior patents and published patent applications of co-workers and collaborators are not prior art either for purposes of determining novelty (35 U.S.C. 102) or nonobviousness (35 U.S.C. 103).

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<sup>4</sup> “The MPEP is commonly relied upon as a guide to patent attorneys and patent examiners on procedural matters. Although the MPEP does not have the force of law, it is entitled to judicial notice so far as it is an official interpretation of statutes or regulations with which it is not in conflict.” *Airbus S.A.S. v. Firepass Corp.*, 793 F.3d 1376, 1380 (Fed. Cir. 2015) (internal quotation marks and citations omitted).

Accordingly, a reference is not prior art under § 102(a)(2) if it was subject to common ownership or obligation to assign as a challenged patent on the effective priority date of the challenged patent.

**2. The '793 patent is not prior art to the '327 patent claims.**

The '793 patent is not prior art under either 35 U.S.C. § 102(a)(1) or § 102(a)(2) and thus is not prior art to the '327 patent.

**(i) The '793 patent is not prior art under § 102(a)(1) because it issued after the undisputed effective filing date of the '327 patent.**

The '793 patent is not prior art under § 102(a)(1). The '793 patent issued on July 21, 2020. '793 patent at (22), (45). Accordingly, the '793 patent is not prior art as a printed publication because it had not issued before April 17, 2020, the undisputed effective filing date of the '327 patent. Ex. A (Pretrial Conf. Tr.) at 9:7–14 (“They are no longer contesting priority, the priority date of the patent. . . . The Court: . . . I can see why it’s moot on that too.”); '327 patent at (60). Moreover, Liquidia has never contended (nor could it) that the '793 patent is prior art under § 102(a)(1). Thus, it is undisputed that the '793 patent is not prior art to the '327 patent under § 102(a)(1).

**(ii) The '793 patent is not prior art under § 102(a)(2) because it is excluded by § 102(b)(2)(C).**

A disclosure otherwise prior art under § 102(a)(2) “shall not be prior art” if, “not later than the effective filing date of the claimed invention,” “the subject matter disclosed and the claimed invention . . . were owned by the same person or subject to an obligation of assignment to the same person.” 35 U.S.C. § 102(b)(2)(C). Here, “the subject matter disclosed” is the '793 patent, and the “claimed invention” is claim 14 of the '327 patent. Because both were owned by UTC on April 17, 2020—the undisputed effective filing date of the '327 patent—the '793 patent “shall not be prior art.” *Id.*

Liquidia cannot seriously dispute common ownership of the '793 patent and the '327 patent on the effective filing date of the '327 patent. First, UTC owned both the '810 provisional (which issued as the '327 patent) and the '662 application (which issued as the '793 patent) on April 17, 2020. Noah Byrd testified that the '793 and '327 patents were owned by UTC from the day they were first filed, which includes ownership on April 17, 2020. Ex. D (Trial Tr. Vol. I) 36:3–21; DTX0002 at 1 (22); JTX0001 at 1 (60). Second, Liquidia has conceded common ownership on numerous occasions. D.I. 347 at 108 (Liquidia's Initial Invalidation Contentions at 74 (June 3, 2024)) ("the '327 and '793 patents are commonly owned by UTC"); Ex. F (Liquidia's First Amended Invalidation Contentions at 74 (July 16, 2024)) (same); Ex. B (Liquidia's Oct. 30, 2024 Contentions at 76) (same); *see also United Therapeutics Corp. v. Liquidia Techs. Inc.*, No. 22-2217, ECF No. 21, at 13 (Fed. Cir. Oct. 21, 2022) ("After Liquidia filed its NDA, **UTC filed the application leading to the '793 patent . . .**"); *see also* 37 C.F.R. § 3.73(a) ("The original applicant is presumed to be the owner of an application for an original patent, and any patent that may issue therefrom, unless there is an assignment."). Regardless, it is too late for Liquidia to challenge ownership; it was Liquidia's burden to prove the prior art status of the '793 patent.

Because both the '793 and '327 patents (and underlying applications) were commonly owned by UTC as of the effective filing date, the '793 patent is not prior art to the '327 patent under the common ownership exception defined in § 102(b)(2)(C). Accordingly, the '793 patent cannot be considered as an obviousness reference asserted against the '327 patent.

**C. Because the '793 patent is not prior art, Liquidia's obviousness combination fails.**

Liquidia's obviousness combination cannot succeed without the '793 patent.<sup>5</sup> The Federal Circuit and courts in this District have determined that, where a challenger relies on a document that is ultimately determined not to be prior art, the obviousness combination fails. *See, e.g., Medtronic, Inc. v. Teleflex Innovations S.A.R.L.*, 68 F.4th 1298, 1308 (Fed. Cir. 2023) ("Because Itou does not qualify as prior art, we likewise affirm the Board's holding that [challenger] did not demonstrate by a preponderance of the evidence that the challenged claims of the challenged patents are unpatentable."); *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 449 (Fed. Cir. 1986) (reversing obviousness determination where district court "considered evidence that was not prior art"); *Janssen Pharms., Inc. v. Tolmar, Inc.*, 718 F. Supp. 3d 394, 412 (D. Del. 2024) ("Based on the evidence at trial, I find that one of [challenger's] principal references, . . . is not prior art to the [challenged] patent. I also find that a person of ordinary skill in the art would not have found the claimed dosing regimens obvious over the remaining references without" the principal reference). As Dr. Channick admitted, the '793 patent is the only reference on which he relied for the disclosure of the dry powder inhaler limitation of claim 14. Ex. E (Trial Tr. Vol. II) 474:14–475:9.

Nothing in Faria-Urbina 2018 or Saggar 2014 can fill the gap left by omission of the '793 patent. Indeed, the entire reason for Liquidia's reliance on the '793 patent is that the other references say nothing about a dry powder formulation or its use. Where, as here, no prior art teaches a limitation of a claim, hindsight cannot supply that limitation and render the claim obvious. *Zoltek Corp. v. United States*, 815 F.3d 1302, 1313 (Fed. Cir. 2016) ("To imbue one of

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<sup>5</sup> Liquidia's obviousness combination also cannot succeed in invalidating claim 14 of the '327 patent even if the '793 patent is ultimately determined to be prior art to claim 14.

ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.” (quoting *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983)); see also *Glatt Air Techniques, Inc.*, 630 F.3d at 1030. Moreover, by pivoting to some other rationale to substitute for the ’793 patent, Liquidia would effectively be creating a new defense and defying the Court’s order limiting Liquidia to four defenses. D.I. 317, 318. Liquidia made the strategic decision to rely on the ’793 patent because of its claimed subject matter. It must live with that choice. Because Liquidia’s obviousness combination does not teach the dry powder inhaler limitation of claim 14, Liquidia’s has no obviousness defense to claim 14.

## VI. CONCLUSION

Liquidia has no evidence that claim 14 is obvious because the only reference it claims teaches the administration of treprostinil through a dry powder inhaler does not qualify as prior art under 35 U.S.C. § 102. UTC respectfully requests that the Court grant UTC’s motion and enter judgment against Liquidia regarding the validity of claim 14.

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**CERTIFICATE OF SERVICE**

I hereby certify that on June 25, 2025, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on June 25, 2025, upon the following in the manner indicated:

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